provide an interpretation of the patient's neuropsychiatric condition. The neuropsychiatric interpretive EEG assessment aid is used only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The technical parameters of the device, hardware and software, must be fully characterized and must demonstrate a reasonable assurance of safety and effectiveness.

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's condition, must be described in detail in the software requirements specification and software design specification. Appropriate software verification, validation, and hazard analysis must be performed.

(2) The device parts that contact the patient must be demonstrated to be biocompatible.

(3) The device must be designed and tested for electrical safety, electromagnetic compatibility, thermal, and mechanical safety.

(4) Clinical performance testing must demonstrate the accuracy, precision, reproducibility, of determining the EEG-based interpretation, including any specified equivocal zones (cutoffs).

(5) Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value, and negative predictive value per the device intended use. Repeatability of measurements must be demonstrated using interclass correlation coefficients and illustrated by qualitative scatter plot(s).

(6) The device design must include safeguards to prevent use of the device as a stand-alone diagnostic.

(7) The labeling must include the following information:

(i) A warning that the device is not to be used as a stand-alone diagnostic.

(ii) A detailed summary of the clinical performance testing, including any adverse events and complications.

(iii) The qualifications and training requirements for device users including technicians and clinicians.

(iv) The intended use population and the intended use environment.

(v) Any instructions technicians should convey to patients regarding the collection of EEG data.

(vi) Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.

(vii) Where appropriate, validated methods and instructions for reprocessing of any reusable components.

[79 FR 9085, Feb. 18, 2014]

§ 882.1460 Nystagmograph.

(a) *Identification.* A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

(b) *Classification.* Class II (performance standards).

§ 882.1480 Neurological endoscope.

(a) *Identification.* A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

(b) *Classification.* Class II (performance standards).

§ 882.1500 Esthesiometer.

(a) *Identification.* An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180 of this chapter, with respect to